UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE

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In re:

AREDIA and ZOMETA	**No. 3:06-MD-1760**
PRODUCTS LIABILITY LITIGATION	**JUDGE CAMPBELL**
(MDL No. 1760)	**MAGISTRATE JUDGE BROWN**

This Documents Relates to: **All Cases**

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PLAINTIFFS' CASE MANAGEMENT ORDER
CORRECTS DOCKET ENTRY 84

This Case Management Order is hereby entered in all actions in *In re: Aredia® and Zometa® Products Liability Litigation,* No. 3:06-MD-1760 (M.D. Tenn.) ("MDL 1760").

This Order shall apply to all cases currently a part of MDL 1760, as well as all cases subsequently filed in, removed to, or transferred to this Court as part of MDL 1760. In cases subsequently filed in this district, the Clerk shall provide a copy of the Order to each Plaintiff at the time of filing of the complaint. In cases subsequently removed or transferred to this Court, the Clerk shall provide a copy of this Order to each new party upon removal or transfer. This Order vacates any prior case management or scheduling order issued by a federal court prior to the transfer of a case to MDL 1760, including the case management orders entered in matters pending before this Court prior to entry of the Order of the Judicial Panel on Multidistrict Litigation ("JPML") creating this MDL. The local rules of a federal transferor court will not be binding on the parties once a case has been transferred to this MDL so long as the case remains before this transferee court. As it relates to any event or filing in MDL 1760, the term "party" means Plaintiffs collectively and

Novartis Pharmaceuticals Corporation individually. This Order shall be binding on all parties with cases docketed in MDL 1760.

The actions described herein are coordinated for pre-trial purposes, and discovery obtained herein may be used by all parties in all cases.

I. Jurisdiction and Venue.

A. The Plaintiffs contend that jurisdiction exists under 28 USC 1332 because there is diversity of citizenship and the amount in controversy exceeds $75,000 exclusive of interests and costs. Plaintiffs contend that venue is proper pursuantto 28 USC §1391(a)(1) because the Defendant is subject to personal jurisdiction here and is therefore deemed to reside in this district for venue purposes pursuant to 28 USC §1391(c).

B. For the purposes of pre-trial proceedings, Defendant has not challenged the existence of diversity jurisdiction but reserves the right to challenge venue as appropriate under 28 U.S.C. § 1404 or other applicable statutes.

II. Status of Service and Responsive Pleadings.

A. The Plaintiffs have effectuated service on the single defendant of the cases currently in MDL 1760 as of the date of this Order. There is not dispute regarding service in those cases. However, Defendant is not precluded from challenging the sufficiency of service in any case not currently part of MDL 1760.

B. All proceedings in any case transferred to MDL 1760, now or in the future, are stayed except (i) specific proceedings outlined in this Order or any subsequent order of the Court, or (ii) any pending motions to remand presently before this Court. All written discovery requests issued prior to transfer to this Court to which responses have not yet been served are stayed.

III. Parties' Theories of the Case

A. **Plaintiffs' Theory of the Case:** Since, 1991, 1.9 million people have been treated with Aredia. Since 2001, one million people have been treated with Zometa. According to Novartis, Zometa is today the most widely used bisphosphonate in oncology. The Plaintiffs seek compensatory damages and punitive damages for personal injuries. The theoriesof liabilityare strict liability and negligence. In addition, the Plaintiffs seek certification of a class action for the creation of a dental monitoring program for persons exposed to the drugs who do not yet have osteonecrosis of the jaw. The large number of persons treated with Aredia and Zometa establish that, when certified, the class will be made up of thousands of people who have taken both drugs.

Novartis filed a New Drug Application (NDA) for Aredia on December 20, 1989. The NDA was approved by the Food and Drug Administration (FDA) on October 31, 1991. At that time, the approved use was for the treatment of hypercalcemia of malignancy (HCM). Subsequently, Aredia was approved for the treatment of Paget's disease, osteolytic bone metastases of breast cancer and osteolytic lesions of multiple myeloma.

On December 21, 1999, Novartis filed a NDA for Zometa. The NDA was approved by the FDA on August 20, 2001. As of that date, the approved use was for HCM. Subsequently, Zometa was approved for the treatment of multiple myeloma and documented bone metastases from solid tumors.

Both Aredia and Zometa are bisphosphonates. Bisphosphonates contain phosphorus. In 2001, the FDA began receiving reports of osteonecrosis of the jaw (ONJ) associated with bisphosphonate therapy. This should have come as no surprise to Novartis. "Phossy jaw" first appeared in a case series reported in Vienna in 1845. The condition was caused by exposure to white

phosphorous during the manufacture of matches. The average time from first exposure to diagnosis was five years. Occasionally, the period was as short as a few months. Also, it has been reported that once taken, bisphosphonates remain in the body for more than twelve (12) years.

Novartis admits receiving reports of ONJ in cancer patients treated with bisphosphonates as early as December, 2002. As of that date, the labeling for Aredia and Zometa contained no warnings or other information about ONJ. This is so even though the clinical trials for both Aredia and Zometa contained patients with findings consistent with ONJ.

Novartis finally took some action in September, 2003, when the package insert for Zometa was revised to contain the following language under post-marketing experiences in the adverse events section:

> Cases of osteonecrosis (primarily of the jaws) have been reported since market introduction. Osteonecrosis of the jaws has other well documented multiple risk factors. It is not possible to determine if these events are related to Zometa or other bisphosphonates, to concomitant drugs or other therapies (e.g., chemotherapy, radiotherapy. corticosteroid), to patient's underlying disease, or to other comorbid risk factors (e.g., anemia, infection, preexisting oral disease).

There were no changes made at that time to the package insert for Aredia.

In October, 2003, Novartis finally took some action with regard to Aredia when the following paragraph was added to the package insert under post-marketing experiences in the adverse events section:

> Cases of osteonecrosis (primarily of the jaws) have been reported since market introduction. Osteonecrosis of the jaws has other well documented multiple risk factors. It is not possible to determine if these events are related to Zometa or other bisphosphonates, to concomitant drugs or other therapies (e.g., chemotherapy, radiotherapy, corticosteroid), to patients's underlying disease, or to other comorbid risk factors (e.g. anemia, infection, preexisting oral disease).

In 2003, Robert E. Marx, DDS, Chairman of Oral and Maxillofacial Surgeryat the University of Miami School of Medicine, published a letter to the editor of the *Journal of Oral and Maxillofacial Surgery* wherein he described 36 cases of painful bone exposure in the mandible, maxilla or both, that were unresponsive to surgical or medical treatment. These patients had received either Aredia, Zometa, or both.

In November, 2003, the FDA Office of Drug Safety (ODS) began a search of the FDA's Adverse Event Reporting System for reports of cases of osteonecrosis or osteomyelitis associated with the use of Aredia, Zometa, Fosamax, or Actenol. In a memorandum dated August 25, 2004, the ODS identified 139 cases of which 47 had taken Aredia only, 33 had taken Zometa only, and 59 had taken both Aredia and Zometa. The review concluded that the language in both the Aredia and Zometa package inserts needed to be changed to highlightthis adverse event as being associated with the therapeutic class of bisphosphonates. In addition, the review concluded that the labeling should be changed to reflect that the condition could be osetonecrosis, osteomyelitis or a combination of the two.

In 2004, Salvatore L. Ruggiero, DMD, MD, Chief of Oral and Maxillofacial Surgery at the Long Island Jewish Medical Center, in collaboration with others, published an article in the *Journal of Oral and Maxillofacial Surgery* in which he described 63 cases of necrotic lesions in the jaw. All 63 had one thing in common: they had all received chronic bisphosphonate therapy. Of the 63 patients, 57 had taken either Aredia or Zometa, or both.

On March 4, 2005, the Oncologic Drugs AdvisoryCommittee of the FDA conducteda public hearing during which testimony was presented relating to the connection between bisphosphonate therapy and osteonecrosis of the jaw. Part of the testimony included an analysis of the mean time from exposure to the appearance of suspicious findings. For Aredia, the mean time was just under six years; for Zometa, 18 months. The need for monitoring was acknowledged by Novartis and it submitted to the Committee a list of recommendations for the prevention,diagnosis and treatment of osteonecrosis of the jaw. These recommendations are a starting point for the creation of the dental monitoring program sought by Plaintiffs in their complaint and request for class certification. Novartis's recommendations include: education of patients regarding the importance of good dental hygiene and symptom reporting; physical and dental evaluation; and imaging with panoramic radiographs. Novartis further recommended that these evaluations occur at a minimum of every six months.

The facts clearly establish that Novartis knew or should have known of the risk of osteonecrosis and/or osteomyelitis of the jaw at the time it first sold Aredia in 1991 and Zometa in 2001. That knowledge only increased with time, yet Novartis did nothing to warn prescribers or users of Aredia until October, 2003 and of Zometa until September, 2003. Even then, the warnings provided were inadequate and were not made availableto dentists or oral surgeons. This inexcusable failure to warn supports Plaintiffs' claim for punitive damages and the necessity for a dental monitoring program. The facts establish the existence of a readily definable class of thousands of persons who took both Aredia and Zometa and which have already developed, or are at significant risk of developing, osteonecrosis and/or osteomyelitis of the jaw. The funding by Novartis of a dental monitoring program similar to, but more complete than the one recommended to the FDA

earlier this year, will serve to reduce the risk of developing these conditions. It will also lead to a more timely diagnosis and treatment of the conditions should they develop.

B. **Defendant's Theory of the Case:**

Plaintiffs allegedly either have osteonecrosis of the jaw ("ONJ") or are at an increased risk of developing it as a result of their use of Aredia® and/or Zometa®, both of which are distributed by Novartis Pharmaceuticals Corporation ("NPC").[1] Aredia® and Zometa® are used by cancer patients with multiple myeloma, metastases to the bone in certain types of cancers, or hypercalcemia of malignancy. Patients with multiple myeloma or bone metastases from solid cancerous tumors lose bone density as a result of the increased resorption of bone tissue associated with the cancer and are therefore more susceptible to debilitating bone fractures, spinal compression, and other skeletal related events ("SREs"). Hypercalcemia is increased calcium in the blood resulting from the over resorption of the bone. It can result in the excessive distribution of calcium to organs and other locations in the body, resulting in impairment of various systems, coma, and death. Aredia® and Zometa® reduce the number, and delay the time to first onset, of SREs suffered by these patients and reduce the effects of hypercalcemia of malignancy. As a result, these drugs provide significant, scientifically documented benefits to their users by enabling them to enjoy a better quality of life.

ONJ is a rare, ill defined, and poorly understood disease with an unknown etiology. There are multiple risk factors for developing ONJ, including but not limited to trauma to the

[1] Aredia® is the trade name under which NPC distributes the drug pamidronate disodium for intravenous infusion. The Food and Drug Administration ("FDA") first approved it for use in 1991, and Aredia® is indicated for the treatment of hypercalcemia associated with malignancy; Paget's disease of bone; osteolytic bone metastases of breast cancer; and osteolytic lesions of multiple myeloma. Zometa® is the trade name under which NPC distributes the drug zoledronic acid for intravenous infusion. The FDA first approved Zometa® for use in 2001. Zometa® is indicated for the treatment of hypercalcemia of malignancy; multiple myeloma; and bone metastases from solid tumors (including prostate and other cancers).

jaw, dental surgery, cancer itself (particularly multiple myeloma), treatment with corticosteroids, hormone therapy, and poor dental hygiene. Further, there are several other disorders that present with symptoms similar to ONJ, but are in fact distinct disease entities.

Plaintiffs' claims fail for several reasons. First, the claims are preempted. At all times, NPC, in consultation with and with the approval and oversight of the FDA, has provided full and adequate information to physicians prescribing Aredia® and Zometa® regarding the known and/or knowable potential risks associated with the drugs. NPC has provided the medical community with ample, timely and adequate information concerning ONJ as it has become available through FDA-approved changes to its product labeling and by other means. Plaintiffs' state law tort claims alleging that NPC's warnings were deficient conflict with the FDA's regulatory system – the same system that has continuously approved the labeling and marketing for Aredia® and Zometa® – and therefore must be dismissed.

Second, no scientifically reliable evidence establishes a causal relationship between treatment with Aredia® or Zometa® and ONJ. Plaintiffs only refer to unreliable case reports or retrospective chart reviews – none of which are a suitable basis for a causation determination under applicable law. Additionally, no dependable science establishes a mechanism of action regarding how either product allegedly causes ONJ.

Third, under any applicable legal standard, including but not limited to a risk/benefit analysis; the Restatement (Second) of Torts § 402A, Comment K; or Restatement (Third) of Torts Product Liability §§ 4, 6, any alleged undisclosed risk posed by treatment with either or both drugs is outweighed the benefits provided by them, thereby defeating plaintiffs' claims. Aredia® and Zometa® allow terminal cancer patients to engage in more of their normal activities for an expanded period of time because of the reduction in risk of SREs. Even if reliable science

were to establish that ONJ is a possible side effect of using either product (which it currently does not), expert and other testimony will demonstrate that doctors prescribed and will continue to prescribe Aredia® and Zometa® because their benefits clearly outweigh any of the low risks for side effects and would likely do so regardless of what language is or was in place in the labeling.

Fourth, plaintiffs have identified no safer alternative design and have provided no evidence that the state of the art, assumption of risk, the learned intermediary doctrine, or other similar defenses are inapplicable. As discussed above, the labeling has always contained various warnings approved by the FDA as appropriate at the given time.

In addition to the above substantive deficiencies, plaintiffs' request for a dental monitoring class fails to satisfy Federal Rule of Civil Procedure 23's certification requirements. In this MDL, the "general causation" inquiry will focus in part on whether either Aredia® or Zometa® can be isolated as the cause of ONJ in cancer patients receiving chemotherapy, radiation treatments, or other treatments or conditions that are independent risk factors for ONJ. Similarly, the specific causation analysis is inherently individual – it will require an examination of, among other things, each individual's medical history, whether a given individual has ONJ or a "look alike" disease, and what other risk factors for ONJ are present in that plaintiff. Further, plaintiffs suffer from several different cancers and were prescribed the drug(s) by different doctors at different times, thereby potentially receiving different information regarding the risk associated with therapy with Aredia® or Zometa®. In addition to sharing no meaningful common factual issues, plaintiffs seek a nationwide medical monitoring class even though no uniformity exists among various states' laws on either the availability of medical monitoring as either an

independent cause of action or a remedy or on the elements of the underlying medical monitoring cause of action. Class certification is inappropriate in such circumstances.[2]

IV. PRE-TRIAL PROCEEDINGS

A. Stay of Discovery: There shall be a stay of discovery with respect to discovery by Defendant of facts and matters pertaining to the individual plaintiffs in all cases other than the plaintiffs named in the original three cases filed in this court. There shall be no stay of discovery with respect to class certification, Defendant's liability, causation, and facts pertaining to and damages claimed by Plaintiffs named in the original three cases filed in this Court. The docket numbers of the three original cases filed in this Court are 3:05-cv-00718, 3:05-cv-00716, and 3:05-cv-00719. Notwithstanding the stay herein prescribed, Defendant's counsel shall furnish Plaintiffs' counsel with a proposed questionnaire to be completed by all Plaintiffs. The questionnaire shall be approved by the Court either by consent of the parties or by appropriate motion practice. Following completion of this questionnaire by Plaintiffs, Defendant's counsel may propose to the Court one or more cases on which the stay of discovery should also be lifted.

B. Rule 26(a)(1) Disclosures: The Defendant and the Plaintiffs in the three original cases filed in this Court have made their Rule 26(a)(1) disclosures. No deadline for Rule 26(a)(1) disclosures by other plaintiffs shall be fixed at this time. The Defendant's previous Rule 26(a)(1) disclosure in the original cases may be used by the Plaintiffs in all cases.

C. **Meeting of Counsel and Parties to Discuss Settlement Prospects:** At this stage of the proceedings, the parties are in agreement that settlement is unlikely and also

[2] For many of the same reasons, the individual plaintiffs' claims are not properly joined in one action, even under the permissive standards of Federal Rule of Civil Procedure 20(a). *See Thorn, et al. v. Novartis Pharm. Corp.*, No. 3:04-CV-586 (E.D. Tenn., August 30, 2005) (Docket #s 73, 74) (Jordan, S.J.) (denying joinder in part because proposed plaintiffs' claims did not arise out of the same transaction or occurrence as pending claims.). The personal injury claims are also ill suited for certification under Rule 23.

believe that ADR would not be productive.

D. **Status of the Issues Presented:** The issues and facts in this case are in dispute at this time.

E. Other claims: At this time the parties are not aware of the need for any counterclaims, cross-claims, third-party claims, joinder of the other parties or claims. Should the parties become aware of the need for such pleadings, they will inform the other.

F. Admission of Fact and/or Stipulations to Authenticity: The parties shall request admissions of fact and/or stipulations regarding the authenticity of documents pursuant to FRCP 36.

G. Liaison Counsel/Committee Structure: The court designates Charles Patrick Flynn to serve as Liaison Counsel for the Plaintiffs and directs that Liaison Counsel confer with Defendant's counsel and file this order on before July 13, 2006. A separate order designating the duties of Liaison Counsel, providing the initial structure of committees of Plaintiffs' counsel and their duties shall also be tendered by Liaison Counsel. Any party objecting to any portion thereof may object within ten days after its filing.

H. Document Production Protocol/Confidentiality Agreement: Defendant will furnish to Plaintiffs on or before July 6, 2006, Defendant's proposed document production protocol which will include electronic word searchable document production. On or before July 14, 2006, Defendant will furnish Plaintiffs a proposed confidentiality agreement which shall be approved by the Court and which will permit Plaintiffs' counsel, Plaintiffs' experts, and the respective necessary staff for counsel and experts to execute the confidentiality agreement and then have access to the documents and confidential materials produced in this case.

I. Counsel Communications: In addition to the local rule requirement of counsel

communication before submission of discovery disputes to the Court, counsel shall attempt to confer in good faith to resolve all issues before submission of the matter to the court. Further, discovery disputes shall be informally brought to the attention of the Magistrate Judge by telephone before submission of any discovery dispute to the court by motion.

J. Schedule of Pretrial Proceedings: The following schedule shall govern proceedings in this cause:

1. On or before February 2, 2007, the Plaintiffs shall serve the Defendant with affidavits (by lay or expert witnesses) and expert reports upon which Plaintiffs are relying with respect to class certification (including without limitation an expert report or expert affidavit by each person the Plaintiff may call to testify as an expert witness at the hearing on class certification).

2. On or before March 2, 2007, the Defendant shall serve the Plaintiffs with affidavits (by lay or expert witnesses) and expert reports upon which the Defendant is relying with respect to class certification (including without limitation an expert report or expert affidavit by each person the Defendant may call to testify as an expert witness at the hearing on class certification).

3. On or before April 20, 2007, Plaintiffs shall give notice in writing, including a definition of the proposed class, of their desire to be granted class certification.

4. On or before May 21, 2007, the Defendant shall file its memorandum in opposition to class certification.

5. On or before June 15, 2007, Plaintiffs shall file their memorandum in support of class certification under Fed. Rule Civ. Proc. 23(b)(2) and/or 23(b)(3).

6. On or before June 30, 2007, Defendant shall file its reply memorandum in further opposition to class certification.

7. If the Court requests the parties to submit proposed findingsof fact and conclusions law on class certification, these shall be due as the court may require.

8. On or before April 3, 2007, the parties shall file motions to name additional parties or otherwise amend their pleadings.

9. On or before April 27, 2007, the Plaintiffs shall provide the Defendant with Plaintiffs' Rule 26(a)(2) disclosures and serve Defendant with reports or affidavits of testifying experts on issues common to all of plaintiffs' cases and all issues in the case(s) set for trial in the Middle District of Tennessee pursuant to this Order.

10. On or before May 28, 2007, the Defendant shall provide the Plaintiffs with its Rule 26(a)(2) disclosures and serve the Plaintiff with reports of affidavits of testifying experts on issues common to all of Plaintiffs' cases and all issues in the case(s) set for trial in the Middle District of Tennessee pursuant to this Order.

11. On or before June 1, 2007, all fact-based discovery in cases in which the stay on discovery has been lifted shall be completed.

12. On or before June 11, 2007, the Plaintiffs may supplement the Plaintiffs' expert reports or affidavits. Except for good cause shown, further supplementation shall be permitted thereafter. Opportunity for supplementation as it relates to expert reports or affidavitsis not intended to excuse the Plaintiffs from fully complying with the initial expert disclosureobligation, but instead is intended to provide for disclosure of expert work that is truly in the nature of rebuttal of the Defendant's expert(s).

13. All discovery motions, except as may subsequently arise with respect to experts, in case(s) set for trial in the Middle District of Tennessee pursuant to this Order shall be filed on or before June 18, 2007.

14. On or before June 22, 2007, the Defendant may supplementit expert reports or expert affidavits. Except for good cause shown, no further supplementation shall be permitted. The opportunity for supplementation, as it relates to expert reports or affidavits, is not intended to excuse the Defendants from fully complying with the initial expert disclosure obligation, but instead is intended to provide for disclosure of expert work that is truly in the nature of sur-rebuttal of the Plaintiff's experts(s).

15. On or before August 31, 2007, discovery of experts common to all cases and all experts in case(s) set for trial in the Middle District of Tennessee pursuant to this Order shall be completed and any discovery motions pertaining to experts shall be filed.

16. On or before September 30, 2007, in case(s) set for trial in the Middle District of Tennessee pursuant to this Order the parties shall file all motions for summary judgment, other potentially dispositive motions (includingFRCP 12 motions),motions relatingto the admissibility of expert testimony, and motions for Daubert hearings.

17. On or before November 5, 2007, in case(s) set for trial in the Middle District of Tennessee pursuant to this Order, the parties shall file motions in limine and any motions objecting to expert testimony. Any response to such motion shall be filed by November 12, 2007.

18. Counsel shall submit a joint proposed pre-trial order to the Court by November12, 2007, in case(s) set for trial in the Middle District of Tennessee pursuant to this Order. The pre-trial order shall contain: (1) a recitation that the pleadings are amended to conform to the pre-trial order and that the pre-trial order supplants the pleadings; (2) a statement of the basis for jurisdiction of this Court; (3) a short summary of Plaintiffs' theory (no more than one page); (4) a short summary of Defendant's theory (no more than one page); (5) a statement of the issues, including designation of which issues are for the jury and which are for the Court; (6) a statement of the relief sought; (7) a

summary of any anticipated evidentiary disputes; and (8) and estimate of the anticipated length of trial.

19. Also, by November 12, 2007, in case(s) set for trial in the Middle District of Tennessee pursuant to this Order, the parties shall submit to the Court:

(a) A joint proposed jury instruction and verdict forms as follows:

Counsel shall exchange proposed jury instructions on substantive law of this specific case and proposed verdict forms and confer to reach agreement. Thereafter, counsel shall jointly prepare and file a set of agreed, proposed, case-specific jury instructions and verdict forms. Each proposed jury instruction shall begin with a new page and shall include the citations to supporting authorities. Counsel shall separately file any disputed jury instructions or verdict forms.

Certain standard non-case specific jury instructions generally used by the Court are available on the Court's website: http//www.tnmd.uscourts.gov/campbell.html. Counsel with internet access shall file any objections to these standard jury instructions.

If possible the parties shall submit a word perfect compatible computer disc of the agreed proposed jury instructions and verdict forms with hard copy;

(b) witness lists, except for witnesses solely for impeachment in accordance with FRCP 26(a)(3);

(c) exhibit lists, except for documents solely for impeachment in accordance with FRCP 26(a)(3); and

(d) any stipulations.

20. Counsel for the parties in case(s) set for trial in the Middle District of Tennessee pursuant to this Order shall appear for a pre-trial conference in this Court on November 19, 2007 at

9:00 a.m. All lawyers who will participate in the trial must attend the pre-trial conference.

21. One or more cases subsequently to be determined shall be set for trial on November 27, 2007. It is anticipated that the trial of this cause will take three (3) weeks.

It is so **ORDERED** this _____ day of _____, 2006.

_____
JOE B. BROWN
United States Magistrate Judge

APPROVED FOR ENTRY:

_____/s/_____
CHARLES PATRICK FLYNN
Flynn and Radford, Attorneys, P.C.
Suite 150, 320 Seven Springs Way
Brentwood, TN 37027
(615) 370-9448
Email: pflynn@flynnandradford.com
LIAISON COUNSEL FOR PLAINTIFFS

_____
KATHARINE R. LATIMER
Spriggs & Hollingsworth
1350 I Street, NW, 9th Floor
Washington, DC 20005
Email: klatimer@spriggs.com
COUNSEL FOR DEFENDANT

CERTIFICATE OF SERVICE

I hereby certify that I have on this 20th day of July, 2006, served a true and correct copy of the foregoing Case Management Order by operation of the Court's Electronic Case Filing System, on the following:

Catherine R. Baumer
Spriggs & Hollingsworth
1350 I Street, NW, 9th Floor
Washington, DC 20005
(202) 898-5800

(202) 682-1639 (fax)
cbaumer@spriggs.com

Andrew L. Colocotronis
Baker, Donelson, Bearman, Caldwell & Berkowitz, P.C.
900 South Gay Street
2200 Riverview Tower
Knoxville, TN 37902
(865) 549-7000
acolocotronis@bakerdonelson.com

Jim C. Curtis
Kemp Smith, LLP
221 N Kansas St., Suite 1700
El Paso, TX 79901
(915) 533-4424
(915) 546-5360 (fax)
jcurtis@kempsmith.com

Jeffrey A. Dickey
Spriggs & Hollingsworth
1350 I Street, NW, 9th Floor
Washington, DC 20005
(202) 898-5853
(202) 682-1639 (fax)
jdickey@spriggs.com

Penelope A. Dixon
Carlton Fields, P.A.
P.O. Box 3239
4221 W. Boy Scout Blvd., Suite 1000
Tampa, FL 33601-3239
(813) 223-7000
(813) 229-4133 (fax)
pdixon@carltonfields.com

Donald W. Fowler
Spriggs & Hollingsworth
1350 I Street, NW, 9th Floor

Washington, DC 20005
(202) 898-5800
(202) 682-1639 (fax)
dfowler@spriggs.com

Anne Marla Friedman
Spriggs & Hollingsworth
1350 I Street, NW, 9th Floor
Washington, DC 20005
(202) 898-5856
(202) 682-1639 (fax)
annefriedman@hotmail.com

Edward W. Gerecke
Carlton Fields, P.A.
P.O. Box 3239
4221 W. Boy Scout Blvd., Suite 1000
Tampa, FL 33601-3239
(813) 223-7000
(813) 229-4133 (fax)
egerecke@carltonfields.com

Joe G. Hollingsworth
Spriggs & Hollingsworth
1350 I Street, NW, 9th Floor
Washington, DC 20005
(202) 898-5800
(202) 682-1639 (fax)
jhollingsworth@spriggs.com

Robert E. Johnston
Spriggs & Hollingsworth
1350 I Street, NW, 9th Floor
Washington, DC 20005
(202) 898-5800
(202) 682-1639 (fax)
rjohnston@spriggs.com

Katharine R. Latimer
Spriggs & Hollingsworth
1350 I Street, NW, 9th Floor
Washington, DC 20005
(202) 898-5800

(202) 682-1639 (fax)
klatimer@spriggs.com

Stephen E. Matasich
Day Ketterer, Ltd.
Millennium Center
200 Market Ave., N., Suite 300
P.O. Box 24213
Canton, OH 44701-4213
(330) 455-0173
(330) 455-2633 (fax)
sematasich@dayketterer.com

Mark N. Osborn
Kemp Smith, LLP
221 N Kansas Street, Suite 1700
El Paso, TX 79901
(915) 533-4424
(915) 546-5360 (fax)
mosborn@kempsmith.com

Peter G. Pappas
Nexsen, Pruet, Adams & Kleemeier, PLLC
P.O. Box 3463
Greensboro, NC 27402
(336) 373-1600
(336) 273-5357 (fax)
ppappas@npaklaw.com

Yanika C. Smith
Baker, Donelson, Bearman, Caldwell & Berkowitz, PC
Commerce Center, Suite 1000
211 Commerce Street
Nashville, TN 37201
(615) 726-5600
ysmith@bakerdonelson.com

Ethan D. Stein
Gibbons, Del Deo, Dolan, Griffinger & Veccione
One Pennsylvania Plaza, 37th Floor
New York, NY 10119-3701
(212) 649-4700
(212) 333-5980 (fax)

estein@gibbonslaw.com

Alicia M. Wyler
Day Ketterer, Ltd.
Millennium Center, Suite 300
200 Market Ave., North
P.O. Box 24213
Canton, OH 44701-4213
(330) 455-0173
(330) 455-2633 (fax)
amwyler@dayketterer.com

Andy L. Allman
Kelly, Kelly & Allman
629 E. Main Street
Hendersonville, TN 37075
(615) 824-3703
kellykellyallman@comcast.net

Russell H. Beatie
Beatie & Osborn, LLP
521 Fifth Ave., Suite 3400
New York, NY 10175
(212) 888-9000
(212) 888-9664 (fax)
bhunter@bandolaw.com

Robert W. Briley
Briley Law Group, PLLC
511 Union Street, Suite 1610
Nashville, TN 37219
(615) 986-2684
rob@brileylaw.com

Myers Carroll Cayer
Terrell, Hogan
233 E. Bay Street, Suite 800
Jacksonville, FL 32202-3451
(904) 632-2424
(904) 632-0549 (fax)
cayer@terrellhogan.com

Pamela J. Diedrich
Mason, Cawood & Hobbs, PA
69 Franklin Street
Annapolis, MD 21401
(410) 269-6620
(410) 269-5452 (fax)
pjd@mkc-law.com

Robert G. Germany
Pittman, Germany, Roberts & Welsh, LLP
410 S. President Street
Jackson, MS 39201
(601) 948-6200
(601) 948-6187 (fax)
rgg@pgrwlaw.com

Clinton L. Kelly
Kelly, Kelly & Allman
629 E. Main Street
Hendersonville, TN 37075
(615) 824-3703
(615) 822-7339 (fax)
kellykkellyallman@comcast.net

Fred Dulin Kelly
Kelly, Kelly & Allman
629 E. Main Street
Hendersonville, TN 37075
(615) 824-3703
(615) 822-7339 (fax)
kellykellyallman@comcast.net

Roy Lenard Mason
Mason, Cawood & Hobbs, PA
69 Franklin Street
Annapolis, MD 21401
(410) 269-6620
(410) 269-5452 (fax)
rmason@mkc-law.com

Philip J. Miller
Beatie & Osborne
521 Fifth Avenue, 34th Floor
New York, NY 10175
(212) 888-9000
(212) 888-9664 (fax)
pmiller@bandolaw.com

Daniel A. Osborn
Beatie & Osborne
521 Fifth Avenue, 34th Floor
New York NY 10175
(212) 888-9000
(212) 888-9664 (fax)
dosborn@bandolaw.com

Crymes G. Pittman
Pittman, Germany, Roberts & Welsh, LLP
410 S. President Street
Jackson, MS 39201
(601) 948-6200
(601) 948-6187 (fax)
cgp@pgrwlaw.com

Joseph E. Roberts, Jr.
Pittman, Germany, Roberts & Welsh, LLP
410 S. President Street
Jackson, MS 39201
(601) 948-6200
(601) 948-6187) fax)
jer@pgrwlaw.com

John O. Threadgill
Threadgill Law Firm
9724 Kingston Pike, Suite 701
Knoxville, TN 37922
(865) 588-4100
(865) 588-4120
jthreadgill@threadgillfirm.com

Windle Turley

Law Offices of Windle Turley, P.C.
6440 N. Central Expressway
1000 Turley Law Center
Dallas, TX 75206
(214) 691-4025
(214) 361-5802 (fax)

Bart T. Valad
Law Firm of Bart T. Valad, PLLC
10640 Main Street, Suite 200
Fairfax, VA 22030
(703) 352-4820
bvalad@valadlaw.com

John C. Weisensell
Bernlohr & Wertz
301 Nantuck Building
23 S. Main Street
Akron, OH 44308
(330) 434-1000
(330) 434-1001 (fax)
jack@b-wlaw.com

Fred Cromwell Isaacs
Foerster, Isaac & Yerkes, P.A.
2468 Atlantic Boulevard
Jacksonville, FL 32207
US
(904) 396-3160
Fax: (904) 348-0921
fisaac@fly-attorneys.com

Michael F. Seelie
Michael F. Seelie, P.A.
2468 Atlantic Boulevard
Jacksonville, FL 32207
US
(904) 858-1898
Fax: (904) 858-1898
mseelie@comcast.net

/s/
Charles Patrick Flynn